



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

January 17, 2002

Sharon W. Brown
Director, Drug Regulatory Affairs
Berlex Laboratories, Inc.
P.O. Box 1000
Montville, NJ 07045

Dear Ms. Brown:

Your petition requesting the Food and Drug Administration to not recommend the Mylan estradiol transdermal system as a generic substitute to the Cliamara once-a-week estradiol transdermal system was received by this office on 01/16/02. It was assigned docket number 02P-0029/CP 1 and it was filed on 01/17/02. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Dockets Management Branch

02P-0029

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